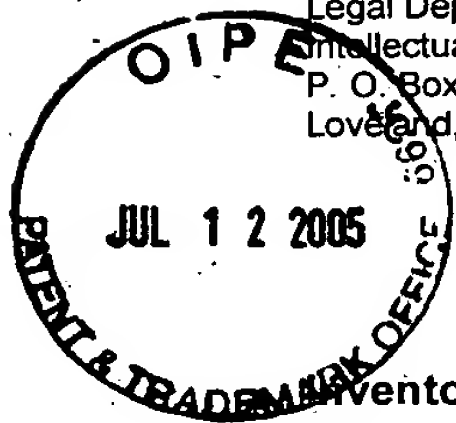


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ATTORNEY DOCKET NO. 10010326-2



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s): Herbert F. Cattell

Serial No.: 09/919,555

Examiner: Betty J. Forman

Filing Date: July 31, 2001

Group Art Unit: 1634

Title: CHEMICAL ARRAY READING

COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria VA 22313-1450

TRANSMITTAL OF REPLY BRIEF

Sir:

Transmitted herewith is the Reply Brief with respect to the Examiner's Answer mailed on 05-16-2005. This Reply Brief is being filed pursuant to 37 CFR 1.193(b) within two months of the date of the Examiner's Answer.

(Note: Extensions of time are not allowed under 37 CFR 1.136(a))

(Note: Failure to file a Reply Brief will result in dismissal of the Appeal as to the claims made subject to an expressly stated new grounds of rejection.)

No fee is required for filing of this Reply Brief.

If any fees are required please charge Deposit Account 50-1078.

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Respectfully submitted,

Herbert F. Cattell

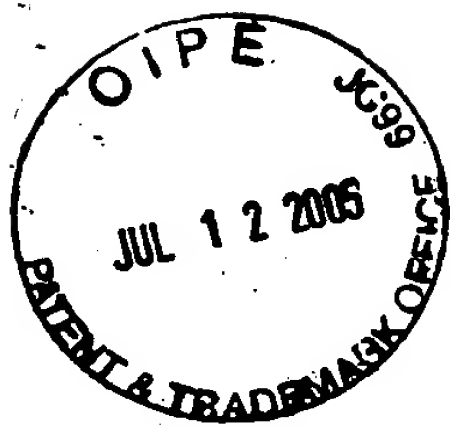
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EV577673466US

<b>REPLY BRIEF</b>  Address to: Mail Stop Appeal Brief- Patents Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	Application Number	09/919,555
	Confirmation Number	4382
	Attorney Docket No.	10010326-2
	Filing Date	July 31, 2001
	First Named Inventor	Herbert F. Cattell
	Examiner	Betty J. Forman
	Group Art	1634
	Title	Chemical Array Reading

Sir:

This Reply Brief is filed in response to the Examiner's Answer dated May 16, 2005 and is further in support of Appellants' appeal filed March 15, 2005. In the Examiner's Answer, no claims have been allowed, and claims 1, 2, 4-16 and 45-54 are still pending. In addition, the Examiner's answer contained no new grounds of rejection. For completeness, this Reply Brief addresses all of the issues on Appeal.

In the unlikely event that the fee transmittal or other papers are separated from this document and/or other fees or relief are required, appellants petition for such relief, including extensions of time, and authorize the Commissioner to charge any fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 which may be required by this paper, or to credit any overpayment, to deposit account number 50-1078, reference no. 10010326-2.

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**REAL PARTY IN INTEREST**

The inventors named on this patent application assigned their entire rights to the invention to Agilent Technologies, Inc.

**RELATED APPEALS AND INTERFERENCES**

There are currently no other appeals or interferences known to Appellants, the undersigned Appellants' representative, or the assignee to whom the inventors assigned their rights in the instant case, which would directly affect or be directly affected by, or have a bearing on the Board's decision in the instant appeal.

**STATUS OF THE CLAIMS**

The present application was filed on July 31, 2001 with claims 1-44. Claims 1-44 were subjected to a restriction requirement and on February 2, 2002 a provisional election was made with traverse to prosecute the invention of Group I, Claims 1-16. During prosecution of the application, Claims 3 and 15-44 were cancelled and new Claims 45-54 were added. Accordingly, Claims 1, 2, 4-16 and 45-54 are pending in the present application and are appealed herein.

All of the pending Claims 1, 2, 4-16 and 45-54 shown in the attached Appendix remain pending, rejected, and appealed herein.

**STATUS OF AMENDMENTS**

During the course of prosecution, amendments were filed on March 17, 2003, amending Claims 1-4, 6, 7, and 9-16, and adding Claims 45 and 46, which amendments were entered. Amendments were filed on December 10, 2003, amending Claims 1, 2, and 10, and canceling withdrawn Claims 17-44, which amendments were entered. On May 18, 2004 an amendment was filed amending Claim 1, 2, and 10, and adding Claims 47-54, which amendment was entered. Thus, Claims 1, 2, 4-16 and 45-54 are pending and appealed, which claims are recited in the attached Appendix.

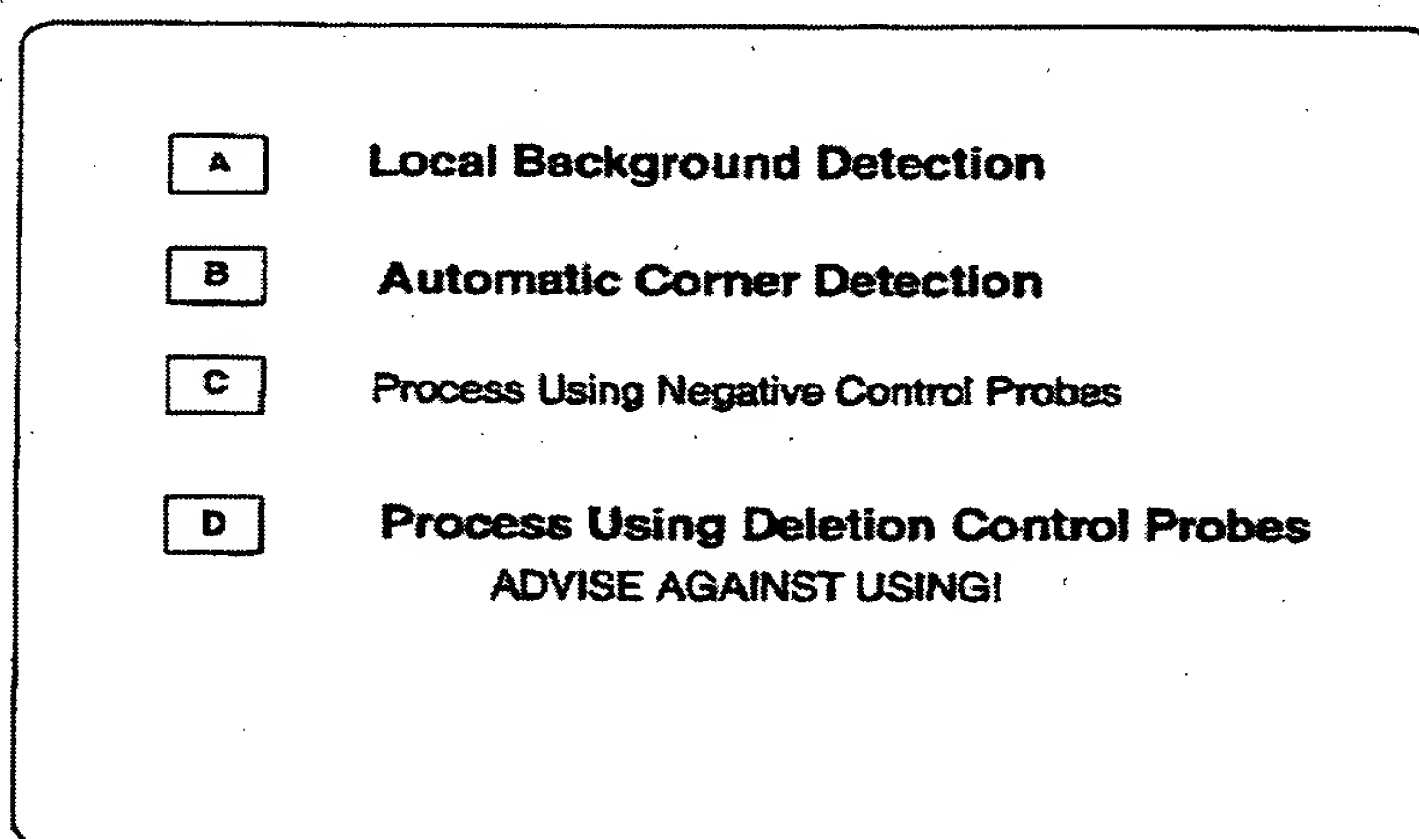
**SUMMARY OF THE CLAIMED SUBJECT MATTER**

The pending claims of the application are directed to methods of generating an addressable array of chemical moieties on a substrate. (Specification, page 3, lines 17-

21). The addressable array of chemical moieties produced by the subject methods (among other utilities) find use in diagnostics, screening and gene expression analysis (Specification, page 1, lines 5-7).

With respect to the invention as claimed in first independent Claim 1, this claim is directed to a method having three recited steps. The first step of the claim is to deposit the chemical moieties, such as different sequence biopolymers, onto different regions of the substrate so as to fabricate the array (Specification, page 3, lines 20-21). Examples of biopolymers are provided in the specification on page 7, line 27 through page 8, line 21.

In the next step of the method claimed in first independent Claim 1, before the array is exposed to a sample, array related data is saved in a memory. The saved array related data includes instructions for: (a) selecting one or more machine readable algorithms for use by a processor on how to read an array; or (b) machine readable algorithm for use by a processor on how to process data from an array following reading of the array (Specification, page 3, line 21-22). Representative use of the array related data is provided in the specification on page 17, line 29 through page 18, line 26. Figure 4, reproduced below, exemplifies how possible selections of different algorithms for reading the array or processing data from the array are modified in response to the array related data saved in memory.



As such, Claim 1 includes a positive step of recording specific types of data in a memory. The stored data is not just any type of Data, but specifically

delineated types of data, i.e., instructions for directing a processor how to read an array or how to process data from an array.

In the final step of the method of Claim 1, the fabricated array is shipped and the array related data is forwarded to a location remote from where the array is fabricated (specification page 3, line 29 through page 4, line 2).

Independent Claim 2 claims a method analogous to Claim 1, but further specifies that the array related data is saved in association with an identifier so that the array related data can be retrieved from the memory using the identifier. The embodiments of independent Claim 2 are described in the specification at page 4, line 3 to line 21. Dependent claim 4 specifies that the chemical moieties are biopolymers and dependent claim 5 specifies that the biopolymers are DNA, e.g., as described in the specification page 7, line 27 through page 8, line 21. Dependent Claim 6 specifies that where the memory is a database, the method additionally includes retrieving the array related data from the memory and communicating the retrieved data to a location remote from the database in response to receiving a communication of the associated identifier from the remote location (specification, page 12, lines 17-31). Dependent Claim 9 specifies a further embodiment wherein the method additionally includes applying a communication address to the substrate or a housing carrying the substrate, which communication address identifies a location from which the array related data will be communicated in response to a received communication of the identifier in association with which the array related data was saved (specification, page 4, line lines 25-31). Dependent Claims 7 and 8 specify that where the memory includes a portable storage medium, the method additionally includes shipping the portable storage medium to a location remote from where the array is fabricated, such as the same location as the array (specification, page 3, line 29 through page 4, line 2).

Independent Claim 10 is directed to a method analogous to Claim 1, but the addressable arrays of chemical moieties are generated on multiple substrates and at a central fabrication station. In addition, the method of Claim 10 further states that the array related data is saved in association with an identifier so that the array related data can be retrieved from the memory using the identifier. This embodiment is reviewed in the specification at page 16, line 28 to page 17, line 7.

Dependent claim 11 specifies that the chemical moieties are biopolymers and dependent claim 12 specifies that the biopolymers are DNA, e.g., as described in the specification page 7, line 27 through page 8, line 21. Dependent Claim 13 specifies that where the memory is a database, the method additionally includes retrieving the array related data from the memory and communicating the retrieved data to a location remote from the database in response to receiving a communication of the associated identifier from the remote location (specification, page 12, lines 17-31). Dependent Claim 16 specifies a further embodiment wherein the method additionally includes applying the same communication address to each of the substrates or to a housing carrying the substrate, which communication address identifies a location from which the array related data will be communicated in response to a received communication of the identifier in association with which the array related data was saved (specification, page 4, line lines 25-31). Dependent Claims 7 and 8 specify that where the memory includes a portable storage medium, the method additionally includes shipping the portable storage medium to a location remote from where the array is fabricated, such as the same location as the array (specification, page 3, line 29 through page 4, line 2).

Dependent Claims 41 and 42 further specify that the array related data of Claims 1 and 2 include an indication as to whether a particular type of control probe is present on the array (specification, page 19, lines 2-17).

Independent Claim 47 is analogous to independent Claim 1, but is specifically directed to the embodiment in which the array related data saved in a memory comprise instructions for selecting one or more machine readable instructions for controlling a scanner on how to read an array or machine readable instructions for controlling a scanner on how to process data from an array following reading of the array. This embodiment is described in the specification at page 17, line 14 through page 19, line 2.

Independent Claim 48 is analogous to independent Claim 1, but is specifically directed to the embodiment in which the array related data saved in a memory comprise instructions for selecting one or more machine readable instructions for controlling a scanner on how to read an array or machine readable instructions for controlling a scanner on how to process data from an array following reading of the array, and where the array related data is saved in association with an identifier so that the array related

data can be retrieved from the memory using the identifier. This embodiment is described in the specification at page 17, line 14 through page 19, line 2.

Dependent Claim 49 specifies that the chemical moieties are biopolymers and dependent Claim 50 specifies that the biopolymers are DNA, e.g., as described in the specification at page 7, line 27 through page 8, line 21. Dependent Claim 51 specifies that where the memory is a database, the method additionally includes retrieving the array related data from the memory and communicating the retrieved data to a location remote from the database in response to receiving a communication of the associated identifier from the remote location (specification, page 12, lines 17-31). Dependent Claim 54 specifies a further embodiment wherein the method additionally includes applying a communication address to the substrate or a housing carrying the substrate, which communication address identifies a location from which the array related data will be communicated in response to a received communication of the identifier in association with which the array related data was saved (specification, page 4, lines 25-31). Dependent Claims 52 and 53 specify that where the memory includes a portable storage medium, the method additionally includes shipping the portable storage medium to a location remote from where the array is fabricated, such as the same location as the array (specification, page 3, line 29 through page 4, line 2).

**GROUND OF REJECTION TO BE REVIEWED ON APPEAL**

- I. Claims 1, 2, 4-16 and 45-54 stand rejected under 35 U.S.C. § 102(e) as being anticipated by copending Application Serial No 09/775,387.
- II. Claims 1, 2, 4-16 and 47-54 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,180,351.
- III. Claims 1, 2, 4-16 and 47-54 stand rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,968,728 in view of U.S. Patent Application No. 2002/0086319A1.



- IV. Claims 45 and 46 stand rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,968,728 in view of U.S. Patent Application No. 2002/0086319A1, and further in view of U.S. Patent No. 6,215,894.
- V. Claims 1, 2, and 4-16 and 45-54 stand rejected under the judicially created doctrine of obviousness type double-patenting over Claims 1-19 of U.S. Patent No. 6,180,351.
- VI. The previous rejection of Claims 10, and 13-16 under the judicially created doctrine of obviousness type double-patenting over Claims 21-24 of U.S. Patent Application No. 09/775,387 was withdrawn in the Examiner's Answer.

#### **ARGUMENTS**

Each ground of rejection is argued separately below.

- I. Claims 1, 2, 4-16 and 45-54 stand rejected under 35 U.S.C. § 102(e) as being anticipated by copending Application Serial No 09/775,387.

In the Examiner's answer, the Examiner has maintained the rejection of Claims 1, 2, 4-16, 45-54 under 35 U.S.C. § 102(e) as being anticipated by copending Application No. 09/775,387 ('387), which is also owned by the Assignee of the present application.

In maintaining the rejection in the Examiner's Answer, the Examiner alleges on Page 19:

This method is well known in the art, as cited above. The claimed method differs from the prior art only in the content of the data/instructions saved in the memory. The method merely requires the step of saving the data/instructions in a memory. The claimed method does not utilize the saved data/instructions or require algorithm selection. Because the method does not utilize the saved data, the data does not alter or limit any function of the claimed method of generating an array. In summary, the saved data consists of instructions without actual performance thereof required. Therefore, the content of the data does not limit the claimed method.

It is important to note that in the above passage, the Examiner acknowledges that the content of what is saved in the "saving step" of the recited methods is different from any content that is saved in the steps of the cited references that the Examiner is equating to the saving step of the present methods. As such, if the content is afforded patentable weight, as the following discussion demonstrates it should, then the claimed methods are patentably distinguished from the cited art.

As reviewed in the Appellants' previously filed brief, the court in *In re Lowry*, 32 F.3d 1579, (Fed.Cir. 1994), has held that:<sup>1</sup>

"The [PTO] must consider **all** claim limitations when determining patentability of an invention over the prior art" (emphasis added).

As reviewed above, the claimed invention is directed to a method of generating an addressable array of chemical moieties that includes a positive method step of saving in a memory, array related data which includes instructions for selecting one or more machine readable algorithms for use on how to read an array or process data from an array. **As such, the methods require a positive step of saving specific types of data into a memory, and not just any type of data into a memory.**

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<sup>1</sup> *In re Lowry*, 32 F.3d 1579, 1582 (Fed.Cir. 1994).

In the present claims in question, the type of information that is saved in the memory, as recited in the claims, **defines** the step of a process for manufacturing the claimed array. In particular, the type of information that is saved into memory according to the claimed method (e.g., data comprising instructions for selecting one or more machine readable algorithms for use by a processor on how to read an array or machine readable algorithms for use by a processor on how to process data from an array following reading of the array) further defines how specifically the saving step is performed (e.g., to save instructions for selecting one or more algorithms of a certain type). This saving step changes the way in which the array can be subsequently processed. Thus, an array for which instructions for selecting one set of algorithms are saved will be a different article of manufacture from an array for which other instructions are saved since the two arrays will be read differently and/or data obtainable from the array will be processed differently. **Therefore, the type of information that is saved into memory is important and does define the claimed method, since it delineates the claimed method step and specifies what the method practitioner is doing at that step of the recited method.**

In the Examiner's Answer, the Examiner continues to impart no patentable weight to the content that is saved in the present claims. In support of this position, the Examiner asserts that because the claimed method does not utilize the saved data, the content of the saved data does not alter or limit any function of the claimed method.

It is respectfully submitted that the Examiner is incorrect in applying the above reasoning. Although the method does not include a step in which a processor employs the saved instructions, the content selected in the saving step defines how

the saving step is performed in the claimed method of manufacture and impacts the characteristics of the array so produced. In other words, the content saved in the saving step is defining how one practices the saving step, and therefore defines how the overall method of manufacturing an array is performed. As discussed above, an array manufactured when instructions for selecting one set of algorithms is saved is different from an array manufactured when different instructions are saved, since the arrays so produced will necessarily be processed differently (i.e., they will be read differently and/or data obtained from the arrays will be processed differently).

It is incorrect to ignore the nature of the content that is saved in this element of the recited methods simply because the content is not employed per se in the methods. Ignoring the specific nature of the content that is saved in the saving step would be akin to ignoring a specified temperature range recited in a "heating step" of a method of manufacture. For example, if a method of manufacture required one to heat a composition to a temperature between X and Y, a proper analysis of the claims would not ignore the recited temperature range specified in the heating step and just focus on heating per se, such that no patentable weight was imparted to the claimed range to which the composition was heated. Similarly, in the present case one cannot just read the saving step as saving any content, but must look at the specific content that saved as recited in the claimed saving step, since the content that is saved in the present application defines the nature of the saving step, just as the recited temperature range defines the nature of the heating step in the above exemplary method. Accordingly, the content that is saved in the saving step is an element that is due full consideration like any other element of a claimed method.

In maintaining the rejection, the Examiner continues to view the claim not as a method claim but as a product claim, and states that "the instantly claimed stored data is reasonably viewed as being within a kit even though it is within a method claim." As such, the Examiner incorrectly continues to assert that *In re Ngai* (70 U.S.P.Q.2d 1862) is controlling, where the court held that "a new set of instructions in a known product merely teaches a new use for an existing product."

However, as reviewed above, the claims at issue in the present application are method claims. Unlike the facts before the court in *In re Ngai*, there is no question that the element of the claim that specifies what is saved in the saving step is an element that defines how the method is performed. Unlike a set of instructions in a kit of reagents, in order to practice the method claims of the present application, one must save the specified type of instructions. As such, the content that is specifically saved in the saving step of the claimed methods is not merely teaching a new use of an existing product, but is instead defining how the saving step is specifically performed. As such, the holding of *In re Ngai* is not applicable to the claims of the present application.

**In sum, the Examiner cannot discount the recited positive step of specifically saving instructions for a processor, since the claims of the present application are directed to methods of making an array. The content that is specifically saved in the saving step of the claimed methods defines the claimed methods because it delineates how the saving step is performed.**

Turning now to the specific rejection over the '387 patent, the Examiner asserted that the co-pending '387 application discloses saving in memory array related data comprising machine readable instructions for reading the array and/or instructions for processing the array (Office Action dated February 18, 2004, page 3). However, in references to the machine-readable information, the '387 specification states the following:

For each fabricated array 12, processor 140 will generate a corresponding unique identifier and will save (430) this in memory 141 in association with the following (together forming a first set of feature characteristic data 440): **target array layout information** (including the location and identity of biopolymers at each feature); **quality control data** (obtained in step 420); **and biological function data** (434). ('387 Specification ¶ 0040) (emphasis added)

Accordingly, the copending '387 application is directed to a method of using an addressable array that comprises machine-readable information on the array layout, the quality control of the array layout, and the biological function information. Moreover, such data includes information on the function of the target or its complement, or the gene from which they originated ('387 Specification ¶¶0039). In addition, the '387 application provides that "biopolymer identification information" is retrieved and used by the processor during reading of the array ('387 Specification ¶¶0043-0044). For example, the specification provides that if the data indicates that "a particular feature is missing or severely defective than the scanner may simply avoid reading such a feature at all" ('387 Specification ¶¶0044).

In contrast, the claimed invention includes a step of saving into memory **instructions to the processor for selecting one or more machine readable algorithms on how to read and process data from a read array**. As such, the substance of the information saved in memory for the claimed invention is clearly different than the biological function information of the '387 application, **as acknowledged by the Examiner in the Examiner's Answer**. Therefore, the '387 patent fails to teach a method step that includes **saving data comprising instructions for selecting one or more machine readable algorithms** on how to read and process data from a read array, as required by the pending claims.

The Examiner has continued to reject the claims over the '387 application as well as the other references cited in the Final Rejection and reviewed below by continuing to assert that the nature of the instructions recorded onto the medium carry no patentable weight because they represent a mere compilation of facts. As such, the Examiner is holding that the instructions when recorded onto a medium are not statutory subject matter, and therefore the nature of the instructions cannot assertedly carry patentable weight.

In the Final Rejection, the Examiner asserted the following:

While the method requires saving data in memory, **the data saved is deemed non-functional descriptive material because the data does not impart functionality to the claimed method of making the array.** While a method step of storing data is limiting within the method, **the data stored is a mere compilation of facts.**...Applicant presents arguments regarding the intended use for the stored instructions/algorithms... (Office Action dated August 13, 2004, pages 6 and 7) (emphasis added).

In support of this position, the Examiner cited a passage from MPEP § 2106 IV(B)1, which is directed to defining nonfunctional descriptive material.

However, it is respectfully submitted that the Examiner's categorization of the **data stored as a mere compilation of facts** is incorrect. The Applicants maintain that the array related data are not simply a compilation of facts, but are **instructions** (i.e., executable by a processor) for selecting one or more machine readable algorithms for use by a processor on how to read the array or process data from the read array. **Such instructions are data structures that comprise functional descriptive material and not merely facts, such as a compilation of information.** **Furthermore, as delineated above the instructions define the "saving step" of the claimed method.** Accordingly, the instructions themselves do carry patentable weight.

MPEP § 2106 IV(B)(1) specifically provides:

Descriptive material can be characterized as either "functional descriptive material" or "nonfunctional descriptive material." In this context, **"functional descriptive material" consists of data structures and computer programs which impart functionality when employed as a computer component.** (The definition of "data structure" is "a physical or logical relationship among data elements, designed to support specific data manipulation functions." The New IEEE Standard Dictionary of Electrical and Electronics Terms 308 (5th ed. 1993).) "Nonfunctional descriptive material"



includes but is not limited to music, literary works and a compilation or mere arrangement of data.

In contrast, non-functional descriptive material, as defined in the MPEP, is “material that cannot exhibit any functional interrelationship with the way in which computing processes are performed” (MPEP § 2106 IV(B)(1)(b)). Therefore, non-functional descriptive material is material that is simply read by a computing process **and does not impart any affect on how the computing process is performed.**

In contrast to material that is simply read by a computing process, the array related data that is saved in the memory in the method step of the element in question of claimed invention includes **instructions for a for selecting one or more machine readable algorithms for use on how to read an array or process data from an array.** {claim 1 doesn't talk about a computing means.]

The specification, on page 17, lines 29-31, states that the array processor retrieves the array related data that is saved in the step in question and **uses the data to “either control reading of the array or to process information obtained from reading the array.”** Accordingly, the array related data is more than mere facts. The array related data structures make up **functional** descriptive material that has an affect on how the computing process is performed.

The nature of the data recorded to memory in the step in question is analogous to the data recorded onto a computer readable medium in *In re Lowry*. The court in *In re Lowry*, found that the data objects were functionally related to the computer memory. The court reasoned that the data objects, although existing only as:<sup>2</sup> [think the footnote should go at the end of the quote]

“a collection of bits having information about relationships between the ADOs,...facilitated addition, deletion, and modification of information stored in

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<sup>2</sup> *In re Lowry* 32 F.3d 1579, 1583-4 (Fed. Cir. 1994) (citing *In re Gulack*, 703 F.2d at 1386).



the memory. In sum, the ADO's **perform a function**. Gulack requires no more."

In the present claims, the array related information that is recorded in the recorded step [there's no "recording step" per se, did you mean "saving step"?] of the claimed process exists as a collection of information that comprises instructions for selecting one or more machine readable algorithms for use by a processor on how to read an array or how to process data from a read array (as did the data objects of the invention in *In re Lowry*, by facilitating the addition, deletion, and modification of information stored in memory.) The array related information imparts a tangible functional consequence for the produced array by providing information on how to read or process data from the read array in a new and useful manner.

As such, the Examiner cannot discount the nature of the information that is recorded when evaluating the method step in question. The information is not just a compilation of facts, but instructions for directing a processor that impart a tangible functional consequence. Therefore, pursuant to the Guidelines and *In re Lowry* (as acknowledge in the Guidelines cited by the Examiner) constitutes statutory subject matter in its own right.

Since the '387 application discloses the use of "biological function information," such as array layout information, rather than **instructions for selecting one or more** machine readable **algorithms** for use by a processor on how to read an array or how to process data from a read array, the cited application fails to disclose every element found in the claims of the present invention. As such, Claims 1, 2, 4-16, and 45-54 are not anticipated under 35 U.S.C. § 102(e) by the '387 application and this rejection may be withdrawn.

II. Claims 1, 2, 4-16 and 47-54 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,180,351.

Claims 1, 2, 4-16 and 47-54 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,180,351 ('351) to Cattell, which is also owned by the Assignee of the present application.

The '351 patent discloses addressable array of chemical moieties wherein the array includes array layout information, which information "refers to one or more characteristics of the array, such as feature positioning, feature size, and some indication of a moiety at a given location" (Column 6, lines 65-67).

In contrast, the claims of the present invention include a positive step of **saving to memory "instructions for selecting one or more machine readable algorithms for use by a processor on how to read an array or machine readable algorithms for use by a processor on how to process data from an array following reading of the array."**

Accordingly, the substance of the identifier of the '351 patent is clearly different than machine readable instructions of the claimed invention because the '351 identifier provides layout information that is used by the processor in reading the array, but **not positive instructions for the processor on how to read the array or process data from the array.**

In order for a cited reference to anticipate the claimed invention, the reference must disclose each and every element of the claimed invention. Since '351 fails to recite the element of saving instructions for selecting one or more machine readable algorithms for use by a processor on how to read an array or how to process data from a read array, the cited patent fails to disclose every element found in the independent claims of the present invention. As such, Claims 1, 2, 4-16 and 47-54 are not anticipated under 35 U.S.C. § 102(e) by the '351 patent this rejection may be withdrawn.

III. Claims 1, 2, 4-16 and 47-54 stand rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,968,728 in view of U.S. Patent Application No. 2002/0086319A1.

Claims 1, 2, 4-16 and 47-54 stand rejected under 35 U.S.C. § 103 as being unpatentable over Perttunen (U.S. Patent No. 5,968,728), in view of Ellison (U.S. Patent Application No. 2002/0086319A1, filed Nov. 13, 2000).

The present invention is directed to methods of generating arrays of chemical moieties by depositing the moieties onto regions of a substrate, saving in memory array related data which is made up of "instructions for selecting one or more machine readable algorithms for use by a processor on how to read an array or machine readable algorithms for use by a processor on how to process data from an array following reading of the array," and shipping the fabricated array to a location remote from where the array was fabricated.

As such, the claims of the present invention include a positive step of **saving** to memory "instructions for selecting one or more machine readable algorithms for use by a processor on how to read an array or machine readable algorithms for use by a processor on how to process data from an array following reading of the array."

The law is clear that to establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. In re Fine, 5 USPQ2d 1596 (Fed. Cir. 1988); In re Jones, 21 USPQ2d 1941 (Fed. Cir. 1992). Second, there must be a reasonable expectation of success. In re Merck & Co., Inc., 231 USPQ 375 (Fed. Cir. 1986). Finally, the prior art reference, or references when combined, must teach or suggest all the claim limitations. In re Royka, 180 USPQ 580 (CCPA 1974).

The disclosure of Perttunen is limited to a method of generating an addressable array, wherein the arrays include instructions for reading the array or instructions for processing the array saved in memory, which consists of mapping information corresponding to the arrayed molecules. Specifically, with respect to the instructions associated with the disclosed arrays the specification states the following:

A data writing device 37 receives a signal associated with the mapping from the processor 30. The data writing device 37 writes data associated with the mapping directly to the support member 36 or to another member associated with the support member 36. The data can include **data which indicates or encodes the mapping**, and/or **data which identifies the mapping**. Examples of the data writing device 37 include, but are not limited to: (i) a magnetic writing head to write magnetic data to a magnetic storage medium; (ii) a printing device to write printed data to a substrate; (iii) an electronic writing device to write electronic data to an electronic storage device such as a memory; and (iv) an optical writing device to write optical data to an optical storage medium. (column 4, lines 61 through column 5, line 7) (emphasis added)

Accordingly, the machine-readable information disclosed in Perttunen is array mapping information.

The Examiner maintains that Perttunen specifically teaches that the array related data comprises machine-readable instructions for "directing operation of the system" (Office Action page 16, citing Perttunen Column 3, lines 54-67). However, the cited passage refers to the processor (item 30 of Figure 2, which is a block diagram of an embodiment of a system for forming a molecular detection device), which receives instructions for generating the mapping and directs the system which fabricates the arrays. **The instructions referred to in the passage are different than the information written on the array, which are discussed in column 4,**

lines 61-67, and the system referred to in the passage is different than a processor that reads an array and processes data from a read array, as acknowledged by the Examiner in the Examiner's Answer. Therefore, nowhere does Perttunen teach that the array mapping information can direct a processor in reading an array or processing data from a read array.

Accordingly, in addition to not teaching shipping of the fabricated array to a remote location, Perttunen is also deficient in that it fails to disclose, teach or fairly suggest another element of the claimed invention –saving instructions for selecting one or more machine readable algorithms for use by a processor on how to read an array or how to process data from a read array. Specifically, the substance of the information saved in memory of Perttunen is simply array mapping information, i.e., the identification of each moiety and its specific location on the array. In contrast, the information saved in memory of the claimed invention of present application consists of instructions for selecting one or more machine readable algorithms for use by the processor on how to read an array or how to process data from a read array. Clearly, the substance of the information of the claimed invention is considerably different than that of Perttunen.

The Examiner also cited Ellson as teaching shipping the fabricated arrays to end users. Specifically, the Examiner states that Ellson teaches a method for generating an addressable array of chemical moieties comprising depositing moieties onto different regions of the substrate, saving in a memory array related data and shipping the array to a remote location. However, the Applicants stress that the disclosure of Ellson is limited to an array of molecular moieties on a substrate, where the substrate also contains machine-readable information, which includes shipping and billing information, the identity of the molecular moieties, information relating to the means by which the moieties were attached to the substrate, and suggested storage conditions relating to the molecular moieties (see specification, ¶ 0052). Therefore, Ellson also fails to teach or suggest a method that includes a step of saving machine readable instructions for use by a processor on how to read an array or how to process data from a read array.

Clearly, the substance of the information provided with the arrays of Perttunen and Ellson is not the same as that of the claimed invention. The pending claims specify that the information saved in memory is **instructions for selecting one or more** machine readable **algorithms** for use by the processor on how to read the array or how to process information from a read array. Accordingly, the array related information of the claimed invention is more than simply billing/shipping information and array mapping information. Therefore, Ellson fails to meet the deficiency of Perttunen.

As such, Perttunen and Ellson taken alone or in any combination, fail to teach at least one element of the claimed invention – **a positive method step of saving instructions for selecting one or more** machine readable **algorithms** for use by a processor on how to read an array or how to process data from a read array. Since the cited references fail to teach an element of the rejected claims, the cited references fail to render the claimed invention obvious.

As such, claims 1, 2, 4-16 and 47-54 are not rendered obvious under 35 U.S.C. § 103 by Perttunen in view of Ellson. Therefore, this rejection be withdrawn.

IV. Claims 45 and 46 stand rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,968,728 in view of U.S. Patent Application No. 2002/0086319A1, and further in view of U.S. Patent No. 6,215,894.

Claims 45 and 46 stand rejected under 35 U.S.C. § 103 as being unpatentable over Perttunen in view of Ellson, and further in view of Zelany (U.S. Patent No. 6,215,894).

As reviewed above, Perttunen and Ellson taken alone or in any combination, fail to teach at least one element of the claimed invention – **saving instructions for selecting one or more** machine readable **algorithms** for use by a processor on **how to read** an array or **how to process data** from a read array. Since Zelany is

cited solely for its disclosure of including data on the presence or absence of a control probe, the cited combination still fails to make up the deficiency of the substance of the machine readable instructions of the claimed invention. As noted above, the machine readable information of the claimed invention is more than mere billing/shipping information and array mapping information; it includes **instructions for selecting one or more** machine readable **algorithms** for use by a processor on **how to read** an array or **how to process data** from a read array.

Therefore, it is respectfully submitted that since the cited combination of references still fails to teach an element of the rejected claims, they fail to render the claimed invention obvious. As such, the rejection of claims 45 and 46 under 35 U.S.C. § 103 may be withdrawn.

V. Claims 1, 2, 4-16 and 45-54 stand rejected under the judicially created doctrine of obviousness type double-patenting over Claims 1-19 of U.S. Patent No. 6,180,351.

Claims 1, 2, and 4-16 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Pat. No. 6,180,351.

As discussed in further detail above, the '351 patent is directed to a method of generating an addressable array of biopolymers and saving in memory a machine readable array layout information, which "refers to one or more characteristics of the array, such as feature positioning, feature size, and some indication of a moiety at a given location" (Column 6, lines 65-67).

In contrast, information saved to a memory according to the present application is "**instructions for selecting one or more** machine readable **algorithms** for use by a processor on how to read an array or machine readable **algorithms** for use by a processor on how to process data from an array following reading of the array." As discussed in detail above, these **instructions** are different



from the array layout information disclosed in the '351 patent. Therefore, the substance of the information saved in memory of the '351 patent is clearly different than the instructions of the claimed invention, thereby rendering the claimed invention patentably distinct from the '351 patent.

Since the claims of the present application and that of the '351 patent are patentably distinct, the Applicants respectfully submit that this rejection may be withdrawn.

#### SUMMARY

- Claims 1, 2, 4-16 and 45-54 are patentable under 35 U.S.C. § 102(e) over copending Application Serial No 09/775,387. As described above, the '387 application discloses the use of "biological function information," such as array layout information, rather than instructions for selecting one or more machine readable algorithms for use by a processor on how to read an array or how to process data from a read array. As such, Application Serial No 09/775,387 fails to recite a step of ***saving instructions for selecting one or more machine readable algorithms for use by a processor on how to read array or how to process data from a read an array to a memory*** and therefore the cited application fails to anticipate Claims 1, 2, 4-16 and 45-46.
- Claims 1, 2, 4-16 and 47-54 are patentable under 35 U.S.C. § 102(e) over U.S. Patent No. 6,180,351. As described above, the '351 reference fails to recite the element of instructions for selecting one or more machine readable algorithms for use by a processor on how to read an array or how to process data from a read array. As such, Patent No. 6,180,351 fails to recite a step of ***saving instructions for selecting one or more machine readable algorithms for use by a processor on how to read an array or how to process data from a read array to a memory*** and



therefore the cited application fails to anticipate Claims 1, 2, 4-16 and 45-46.

- Claims 1, 2, 4-16 and 47-54 are patentable under 35 U.S.C. § 103(a) over U.S. Patent No. 5,968,728 in view of U.S. Patent Application No. 2002/0086319A1 for reasons described above and because the cited references fail to teach or suggest at least one element of the claimed invention – **saving instructions for selecting one or more** machine readable **algorithms** for use by a processor on how to read an array or how to process data from a read array to a memory.
- Claims 45 and 46 are patentable under 35 U.S.C. § 103(a) over U.S. Patent No. 5,968,728 in view of U.S. Patent Application No. 2002/0086319A1, and further in view of U.S. Patent No. 6,215,894 for reasons described above.
- Claims 1, 2, 4-16 and 47-54 are patentable over Claims 1-19 of U.S. Patent No. 6,180,351 for reasons described above.

**RELIEF REQUESTED**

Appellants respectfully request that the rejections of Claims 1, 2, 4-16 and 45-54 under 35 U.S.C. §102, §103, and obviousness type double-patenting be reversed, and that the application be remanded to the Examiner with instructions to issue a Notice of Allowance.

Respectfully submitted,

Date: 7.12.05

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**APPENDIX OF APPEALED CLAIMS**

1. A method for generating an addressable array of chemical moieties on a substrate, comprising:

(a) depositing the moieties onto different regions of the substrate so as to fabricate the array;

(b) before the array is exposed to a sample, saving in a memory array related data which comprises instructions for selecting one or more machine readable algorithms for use by a processor on how to read an array or machine readable algorithms for use by a processor on how to process data from an array following reading of the array;

(c) shipping the fabricated array, and forwarding the array related data to a location remote from where the array is fabricated.

2. A method for generating an addressable array of chemical moieties on a substrate, comprising:

(a) depositing the moieties onto different regions of the substrate so as to fabricate the array;

(b) before the array is exposed to a sample, saving in a memory array related data which comprises instructions for selecting one or more machine readable algorithms for use by a processor on how to read an array or machine readable algorithms for use by a processor on how to process data from an array following reading of the array, which array related data is saved in association with an identifier so that the array related data can be retrieved from the memory using the identifier;

(c) shipping the fabricated array, and forwarding the array related data to a location remote from where the array is fabricated.

4. A method according to claim 2 wherein the chemical moieties are biopolymers.

5. A method according to claim 4 wherein the biopolymers are DNA.
6. A method according to claim 2 wherein the memory is a database, the method additionally comprising retrieving the array related data from the memory and communicating the retrieved data to location remote from the database in response to receiving a communication of the associated identifier from the remote location.
7. A method according to claim 2 wherein the memory comprises a portable storage medium, the method additionally comprising shipping the portable storage medium to a location remote from where the array is fabricated.
8. A method according to claim 7 wherein the portable storage medium is shipped to the same remote location as the array.
9. A method according to claim 6 additionally comprising applying a communication address to the substrate or a housing carrying the substrate, which communication address identifies a location from which the array related data will be communicated in response to a received communication of the identifier in association with which the array related data was saved.
10. A method of generating, at a central fabrication station, addressable arrays of chemical moieties on multiple substrates, comprising at the central fabrication station for each array:
  - (a) depositing biopolymers onto different regions of a substrate so as to fabricate multiple arrays;
  - (b) before the array has been exposed to a sample, saving in a memory array related data which comprises instructions for selecting one or more machine readable algorithms for use by a processor on how to read an array, or machine readable algorithms for use by a processor on how to process data from a read array following reading of the array, which array related data is saved in association

with an identifier so that the array related data can be retrieved from the memory using the identifier;

(c) applying the identifier to the substrate carrying the array or a housing carrying that substrate; and

(d) shipping each of the fabricated arrays with applied identifier to one or more of locations each remote from the central fabrication station.

11. A method according to claim 10 wherein the biopolymers are polynucleotides.

12. A method according to claim 11 wherein the polynucleotides are DNA.

13. A method according to claim 10 wherein the memory is a database, the method additionally comprising retrieving array related data for arrays from the memory and communicating the data to locations remote from the database in response to receiving a communication of associated identifiers from the remote locations.

14. A method according to claim 10 wherein for each of multiple arrays the array related data and identifier for that array are saved on a memory comprising a portable computer readable storage medium, the method additionally comprising shipping the portable storage mediums to multiple locations remote from the central fabrication station.

15. A method according to claim 14 wherein each of the portable storage mediums are shipped with the fabricated array for which the portable storage medium carries array related data and the identifier, to a same location remote from the central fabrication station from which a set of biopolymers used in fabricating that array was received.

16. A method according to claim 10 additionally comprising applying a same communication address to each of the substrates or housings carrying the

substrates, which communication address identifies a location from which array related data will be communicated in response to a received communication of the identifier saved in association with the array related data.

45. A method according to claim 1 wherein the array related data includes an indication as to whether a particular type of control probe is present on the array.

46. A method according to claim 2 wherein the array related data includes an indication as to whether a particular type of control probe is present on the array.

47. A method for generating an addressable array of chemical moieties on a substrate, comprising:

(a) depositing the moieties onto different regions of the substrate so as to fabricate the array;

(b) before the array is exposed to a sample, saving in a memory array related data which comprises instructions for selecting one or more machine readable instructions for controlling a scanner on how to read an array or machine readable instructions for controlling a scanner on how to process data from an array following reading of the array;

(c) shipping the fabricated array, and forwarding the array related data to a location remote from where the array is fabricated.

48. A method for generating an addressable array of chemical moieties on a substrate, comprising:

(a) depositing the moieties onto different regions of the substrate so as to fabricate the array;

(b) before the array is exposed to a sample, saving in a memory array related data which comprises instructions for selecting one or more machine readable instructions for controlling a scanner on how to read an array or machine readable instructions for controlling a scanner on how to process data from an array following reading of the array, which array related data is saved in association with

an identifier so that the array related data can be retrieved from the memory using the identifier;

(c) shipping the fabricated array, and forwarding the array related data to a location remote from where the array is fabricated.

49. A method according to claim 48 wherein the chemical moieties are biopolymers.

50. A method according to claim 49 wherein the biopolymers are DNA.

51. A method according to claim 48 wherein the memory is a database, the method additionally comprising retrieving the array related data from the memory and communicating the retrieved data to location remote from the database in response to receiving a communication of the associated identifier from the remote location.

52. A method according to claim 48 wherein the memory comprises a portable storage medium, the method additionally comprising shipping the portable storage medium to a location remote from where the array is fabricated.

53. A method according to claim 52 wherein the portable storage medium is shipped to the same remote location as the array.

54. A method according to claim 51 additionally comprising applying a communication address to the substrate or a housing carrying the substrate, which communication address identifies a location from which the array related data will be communicated in response to a received communication of the identifier in association with which the array related data was saved.

**EVIDENCE APPENDIX**

No evidence that qualifies under this heading has been submitted during the prosecution of this application, and as such it is left blank.



**RELATED PROCEEDINGS APPENDIX**

As stated in the *Related Appeals and Interferences* section above, there are no other appeals or interferences known to Appellants, the undersigned Appellants' representative, or the assignee to whom the inventors assigned their rights in the instant case, which would directly affect or be directly affected by, or have a bearing on the Board's decision in the instant appeal. As such this section is left blank.